



Euro Disposables- Import/Export International Business & Market Development e.U.

EU Identification Number: ATU68505129

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Product Name	Urine collecting bag	Type	2000ml	Lot.No.	20140518
Qty.	2500pcs	Accordance	YZB/SU(HUI)0001-2005	Steriled No.	20140519
Sampling date		20140519		Date of Report	2014530
Inspection item	Technical requirement				result
Capacity tolerance	Capacity tolerance of the bag should be $\pm 10\%$.				conformity
Sealing function	Have reflux valve device				conformity
	The heat seal line around the bag should have good sealability and no leakage.				conformity
Linkage strength	Various parts can endure 40N steady pull force and hold for 15 seconds.				conformity
Catheter	The catheter should have good ductility.				conformity
Appearance	The bag should be flexible and clean without any pollution and mechanical impurity.				conformity
	The thickness of catheter should be equal. Any defects such as air bubble, crack, non - plastic material are not allowed.				conformity
	Graduation line should be clear and correct and difficult to drop				conformity
Size of the bag	The length should be $\pm 5\text{mm}$				conformity
	The height should be $\pm 5\text{mm}$				conformity
	Double layers of bag should be more than 0.22mm.				conformity
Size of catheter	The length of catheter should not be less than 600mm				conformity
	Inside diameter of catheter should not less than 3.5mm.				conformity
Deoxidization substrates	The difference of volume of consumed potassium permanganate [c(KMnO ₄ =0.002mol/L)] between inspection solution and blank solution should not be more than 2.0mL.				conformity
PH	Deference of PH and inspection solution should not be more than 1.5				conformity
UV absorbency	The UV absorbency of inspection solution should not be more than 0.1				conformity
EO residua	EO residua of each Scalp Vein Set should not be more than 0.1mg.				conformity
Sterility	There should be sterile				conformity
Pyrogen	There should be no pyrogen				conformity
Hemolysis	There should be no Hemolysis				conformity
Urgent general toxicity	There should be no urgent general toxicity				conformity
Conclusion	conformity				

Test report

Approved by:

Analysed by:

For and on behalf of
ZIBO JIASHANG MEDICAL DEVICE CO., LTD.

Authorized Signature(s)

Professional quality, care for health